

### REMARKS

Claims 1 – 10, 18, and 19 are currently pending. Claims 1 and 18 are the pending independent claims. Claims 1 - 8 stand rejected under 35 U.S.C § 102(e) over U.S. Patent Number 7,271,269 to Antoncic et al. (“Antoncic”). Claims 1 – 8, 18, and 19 stand rejected under 35 U.S.C § 103 over Antoncic and U.S. Patent Application Publication Number 2004/0006237 to Doltizky et al. (“Doltizky”) and U.S. Patent Number 5,608,075 to Campbell et al. (“Campbell”). Claims 1 – 3, 9, 10, 18, and 19 stand rejected under 35 U.S.C § 103 over Antoncic in view of U.S. Patent Application Publication Number 2006/0177498 to Bharatarajan et al. (“Bharatarajan”). Claims 1, 7, 8, and 18 have been amended. No new matter has been introduced by any of these amendments, which are all supported by the disclosure of the original claims and the specification. Reconsideration and allowance of the claims are requested.

Each of the foregoing rejections is respectfully traversed and favorable reconsideration is requested in view of the above amendments and following remarks.

#### The § 102 Rejections

As amended herein, independent claim 1 calls for, *inter alia*, a pharmaceutical composition including an active pharmaceutical susceptible to undesirable polymorphic effects, such as certain salts of losartan, together with a stabilizing substance, wherein the stabilizing substance is present in an amount of from 1 % to about 10 % by weight of the pharmaceutical composition. The Examiner concedes that Antoncic does not anticipate such a composition, assuming the term “about” is removed from the lower end of the range, which Applicants have done, as shown above. However, Applicants wish to note for the record their disagreement with the Examiner’s position that the term “about” must be removed in order for the claims to patentably distinguish over Antoncic. Applicants do not believe the calculated amount of 0.95% stabilizer from Antoncic is within the range of from “about” 1% to about 10% stabilizer as called for in their claims. Nonetheless, in an effort to move prosecution forward, Applicants have amended claim 1 to remove the term “about.” But this should not be taken as a surrender of coverage with respect to values below but nonetheless very near 1 weight percent stabilizer and, depending on the situation, compositions having more than 0.95% total stabilizer may still be found to be near enough to 1% to fall under the scope of Applicants’ current claims. Applicants

do not believe strict precision or exactitude with regard to the ends of the claimed ranges is critical, and Applicants assert that “from 1% to about 10%” should be construed to cover compositions that have more than 0.95% up to about 10% by weight stabilizer.<sup>1</sup>

Based on the amendment to claim 1 and the above discussion, claim 1 should now be deemed to patentably distinguish over Antoncic. The Section 102(e) rejection based thereon should therefore be withdrawn.

Claims 2 - 8 depend from independent claim 1 and contain additional important aspects of the invention. Dependent claims 7 and 8 have been amended so as to be no broader than claim 1. Therefore, in light of the amendments to claims 1, 7, and 8 and the above discussion, dependent claims 2 - 8 also should be deemed to patentably distinguish over Antoncic. Reconsideration and allowance of dependent claims 2 - 8 are respectfully requested.

#### The § 103 Rejections

Claims 1 – 8, 18 and 19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Antoncic and Dolitzky and Campbell.

As indicated in the prior response, Antoncic and the present disclosure are owned by or are subject to an obligation to assign to the same entity. That is, the subject matter of Applicants’ claimed invention and the Antoncic reference were, at the time the invention was made, owned by the same entity or subject to an obligation of assignment to the same entity. According to MPEP § 706(1)(2)(II), the statement herein to this effect by a USPTO-admitted practitioner should be sufficient evidence of this fact, plus, the Examiner appears to recognize as much on page 8 of the instant Office Action. Accordingly, since Antoncic is cited under § 102(e) in a §103 rejection, Antoncic is disqualified as a prior art reference for purposes of any alleged “obviousness” rejection by operation of 35 U.S.C. § 103(c).

All obviousness rejections under §103 depend heavily on the “citeability” of Antoncic as a reference. Without Antoncic, the rejections under § 103 must necessarily fail. Accordingly, the obviousness rejection of Claims 1 – 8, 18, and 19 based on Antoncic combined with Dolitzky and Campbell should be withdrawn.

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<sup>1</sup> Among other things, if “0.95%” falls within “about 1%” as alleged by the Examiner, a position which Applicants do not necessarily agree with, then certainly “1%” should encompass amounts somewhat less than 1% but more than 0.95%.

Claims 1 – 3, 9, 10, 18 and 19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Antoncic in view of Bharatarajan. As indicated above, Antoncic is disqualified as a prior art reference by reason of 35 U.S.C. § 103(c). Bhartarajan alone is not even close. Accordingly, the rejection of claims 1 – 3, 9, 10, 18, and 19 for obviousness based on Antoncic and Bharatarajan also should be withdrawn.

In light of the foregoing, Applicants respectfully request the Examiner reconsider the application, withdraw the rejections, and issue a Notice of Allowance of all pending claims at the earliest possible convenience.

In the event this response is not timely filed, Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our **Deposit Account No. 12-2355**.

Respectfully submitted,

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